

Libtayo (cemiplimab-rwlc)

Libtayo is a programmed death receptor-1 (PD-1) blocking antibody indicated for the treatment of patients with metastatic Cutaneous Squamous Cell Carcinoma (mCSCC) or locally advanced CSCC (laCSCC) who are not candidates for curative surgery or curative radiation.

I. Criteria for Initial Approval

Libtayo will be considered for coverage when **all** of the criteria below are met, confirmed with supporting medical documentation.

- For use in patients age 18 and older.
- Documentation of CSCC, **and that all of the following clinical scenarios are met:**
 - Patient has nodal or distant metastatic disease, locally advanced disease, inoperable or incompletely resected regional disease, or regional recurrence.
 - Patient is not a candidate for curative surgery or curative radiation therapy.
 - Libtayo will be used as a single-agent therapy.
- Documentation that the patient has not received any of the following therapies:
 - Patient has not received previous therapy with a programmed death (PD-1/PD-L1)-directed therapy (e.g., avelumab, pembrolizumab, atezolizumab, durvalumab, nivolumab, etc.), unless otherwise specified.
 - Patient has not received previous therapy with a BRAF-inhibitor (e.g., vemurafenib, dabrafenib, encorafenib, etc.)
 - Patient has not received previous therapy with a cytotoxic T-lymphocyte antigen 4 (CTLA-4) targeting agent (e.g., ipilimumab, etc.) within the four weeks prior to therapy.
 - Patient does not have a history of a solid organ transplant.

II. Criteria for Continuation of Therapy

All of the criteria for initial therapy (in **Section I.**) must be met, **AND** the provider must attest to absence of unacceptable toxicity from the drug and a positive clinical response.

- Examples of unacceptable toxicity include: severe infusion reactions, severe and fatal immune-mediated adverse reactions (e.g., pneumonitis, colitis, hepatitis, endocrinopathies, nephritis/renal dysfunction, skin reactions, etc.)

- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread.

III. Dosing/Administration

Libtayo must be administered according to the current FDA labeling guidelines for dosage and timing. The recommended dosing is as follows:

- 350 mg of Libtayo, as an intravenous infusion over 30 minutes every 3 weeks.

IV. Length of Authorization for Therapy

Libtayo will be authorized for 6 months when criteria for initial approval are met. Continuing therapy with Libtayo will be authorized for 12 months.

V. Billing Code/Information

J9119 – Injection, cemiplimab-rwlc, 1 mg; 1 billable units = 1 mg.

Prior authorization of benefits is not the practice of medicine nor the substitute for the independent medical judgment of a treating medical provider. The materials provided are a component used to assist in making coverage decisions and administering benefits. Prior authorization does not constitute a contract or guarantee regarding member eligibility or payment. Prior authorization criteria are established based on a collaborative effort using input from the current medical literature and based on evidence available at the time.

Approved by MDH Clinical Criteria Committee: 2/23/2021

Last Reviewed Date: 2/23/2021